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Admin Measures for Qualification Criteria of Food Inspection Institutions

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Report Highlights:

On May 31, 2010, the Legislative Affairs Office of the State Council published draft "Administrative Measures on Qualification Criteria of Food Inspection Institutions" for domestic comment. The measure specifies the qualification criteria for food and food additive inspection institutions. The deadline for comments was June 10, 2010 and the regulation will come into force on October 1, 2010. This report contains an UNOFFICIAL translation of the document.

Executive Summary:

On May 31, 2010, the Legislative Affairs Office of the State Council published draft “Administrative Measures on Qualification Criteria of Food Inspection Institutions” for domestic comments. Drafted by AQSIQ, the Measures specify the qualification criteria for food and food additive inspection institutions. The deadline for comments was June 10, 2010 and the regulation will come into force on October 1, 2010. Comments can be sent to: quantt@aqsiq.gov.cn

Thanks go to FDA China for their assistance in the translation of this measure.

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General Information:

BEGIN TRANSLATION

Administrative Measures for Qualification Criteria of Food Inspection Institutions
(Draft for Comments)

Chapter I General Provisions**Article 1 [Legislative Purpose]**

In order to regulate the qualification criteria of food inspection institutions, to reinforce the supervision and administration of food inspection institutions, as well as to enhance the technical capacity and management qualification of food inspection institutions, this set of measures is enacted in accordance with the Food Safety Law of the People’s Republic of China, Provisions of Certification and Accreditation of the People’s Republic of China, and rules set in pursuant law and administrative regulations.

Article 2 [Definition]

Qualification criteria of food inspection institutions in this set of administrative measures means the evaluation and criteria actions by the Certification and Accreditation Administration of the People’s Republic of China, governmental quality supervision and administration departments of respective provinces, autonomous regions as well as municipalities directly under the jurisdiction of central government.

Article 3 [Applicable Scope]

Within the People’s Republic of China, food inspection institutions and institutions engaged in food additive inspections shall abide by this set of measures.

Article 4 [Qualification Criteria System]

The General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China (AQSIQ) integrally manages the qualification criteria duties of food inspection institutions. The Certification and Accreditation Administration of the People’s Republic of China (CNCA) is responsible for the execution, supervision and administration as well as the general coordination duties of the qualification criteria of food inspection institutions.

Governmental quality and technology supervision departments of respective provinces, autonomous regions and municipalities directly under the central government’s jurisdictions (hereafter referred as provincial quality supervision departments), in accordance with assigned

responsibilities, are responsible for the execution, supervision and evaluation of the qualification criteria duties on food inspection institutions in the juristic territories.

Article 5 [Principles for Qualification Criteria]

The principles for qualification criteria of food inspection institutions should be objective, fair, scientific, accurate, open, transparent, highly efficient and convenient. Unnecessarily repetitive criteria and evaluation should be avoided.

Article 6 [Behavioral Requirements on Food Inspection Institutions]

Food inspection institutions and those engaging in inspectional activities should abide by pursuant law, regulations, food safety standards and rules in inspectional norms, respect the science, strictly comply with professional morality, and assure to the society the objectiveness, fairness and accuracy of inspectional data and results.

Chapter II Condition and Procedure on Qualification Criteria

Article 7 [Qualification Criteria]

Prior to engaging in food inspection activities, food inspection institutions should acquire the legal qualification criteria in compliance with pursuant regulations on certification and accreditation. Without qualification criteria, food inspection institutions are not allowed to issue inspectional data and results that can serve as proof.

Article 8 [Condition for Qualification Criteria]

Food inspection institutes should meet the requirements for qualification criteria set by the health administrative authority of the State Council.

Article 9 [Qualification Cognizing Bodies]

Qualification criteria for food inspection institutions which belong to and the establishment of which were approved by the pursuant administrative authority of the State Council should be executed by CNCA. Qualification criteria for food inspection institutions, except for those mentioned above should be executed by provincial quality and supervision administrative departments.

Article 10 [Qualification Criteria Procedure]

Procedure of qualification criteria for food inspection institutions:

- (i) Food inspection institutions who apply for qualification criteria (hereafter referred as applicants) should submit written application to CNCA or provincial quality supervision administrative departments (hereafter referred as qualification granting departments), plus relevant supporting documents in compliance with Article 8 in this set of measures.
- (ii) Qualification granting departments should review the application documents submitted by applicants, and make the decision in writing within five days whether or not to accept the application. For those with incomplete application documents or not in compliance with legitimate format, the applicant should be given the information of all needed documents/materials in one notification.
- (iii) Within 6 months since accepting the application, quality criteria granting departments should proceed and complete the technical review and evaluation of the applicant. Time for evaluation is not inclusive in the set approval time frame. In special circumstance, technical evaluation can last reasonably longer.
- (iv) Within 20 days after the completion of technical review, qualification granting departments should review the results from technical evaluation and make the decision of approval or disapproval. Grant qualification criteria certificates to the approved ones and allow them to use the logo of qualification criteria. Those with disapprovals should be notified in writing with

reasons stated.

Article 11 [Publication of Information]

CNCA and provincial quality supervision departments should periodically publicize a list of food inspection institutions whose qualification criteria has been approved, with information of the institutions' inspection scope and technical capacity; meanwhile, provide the public with channels for inquiry.

Article 12 [Certificates of Qualification Criteria]

Certificates for qualification criteria of food inspection institutions are valid for three years.

Food inspection institutions who need to extend the validity of legitimate qualification criteria should submit the renewal application to the qualification granting departments 6 months prior to the expiry of the certificates.

Article 13 [Rules on Use of the Certificate and Logo]

CNCA unifies the certificate design, numbering rule and logo design of the qualification criteria of food inspection institutions.

Food inspection institutions should properly use the qualification criteria logo and certificates in the food inspection reports that they issue or promotional materials, so as to testify the qualification criteria.

Article 14 [Rules on Alteration]

In any of the below circumstances, food inspection institutions should lawfully apply for alteration to the qualification granting departments:

- (i) Change of inspection items or methods
- (ii) Change of name, location, legal representative(s), authorized signer(s) and technical managers
- (iii) Other significant changes in the food inspection institute

In a case where food institutions apply for qualification criteria for additional inspection items, qualification granting departments should proceed in accordance with Article 10 in this set of measures.

Article 15 [Rules on Emergency and Response]

In the case of significant food safety incident or other food safety emergency when additional inspection items are needed, qualification granting departments should timely initiate the emergency response program, and publicize a list of qualified food inspection institutions.

Chapter III Technical Evaluation

Article 16 [Evaluation Principles]

CNCA sets the evaluation principles for qualification criteria of food inspection institutions, in compliance with the requirements for qualification criteria set by the health administrative departments of the State Council and pursuant regulations in national standards.

Article 17 [Evaluation Panel]

Qualification granting departments should form a technical evaluation team in accordance with requirements of evaluation principles, and conduct technical evaluation on the applicant's basic condition, management system, and inspection capacity etc. Technical evaluation panel should consist of at least two individuals. When necessary, technical experts can also be invited to the evaluation.

Article 18 [Qualification of Evaluation Panel Members]

Those engaging in technical evaluation should have experience in food inspection, research or

management, and strong capability of observation, analysis, judgment and expressions related to evaluation, and are qualified by the qualification granting department's assessment.

Article 19 [Verification of Inspection Capacity]

When evaluating the applicant's inspection capacity, the technical evaluation panel should verify the applicant's relevant inspection experience and credentials of capability in testifying and comparison experiments as well as survey audits. When on-site experiments are needed, evaluation should be conducted in accordance with evaluation principles.

Article 20 [Evaluation Conclusion]

Technical evaluation panel should organize the evaluation within the time frame set in the evaluation principles. In the case of incompliance, technical evaluation panel should notify in writing the applicant of correction within designated period. Failure to correct within designated period or failure to meet the requirements after correction will be concluded as failure in evaluation.

After the evaluation, technical evaluation panel should provide evaluation comments and produce evaluation report, and deliver to the quality granting departments in a timely manner.

Article 21 [Evaluation Responsibility Mechanism]

Technical evaluation panel should timely report to the qualification granting departments of significant problems found in the evaluation of the applicants.

The team leader of technical evaluation panel is responsible for the evaluation activities and evaluation conclusion. Members of the evaluation panel are responsible for their evaluation duties.

Article 22 [Management of Evaluators]

Qualification granting departments should supervise and check the evaluation panel and panel members' evaluation activities, and organize trainings on technical skills for panel members, so as to improve the panel members' evaluation capability and qualification.

Article 23 [Forbidden Rules on Evaluation Panel Members]

If an evaluation panel member is in any of the below circumstances, qualification granting departments should suspend or cease the member's engagement in the evaluation, depending on the seriousness of the case:

- (i) Conduct evaluation activities in incompliance with the rules set in the evaluation principles for qualification criteria of food inspection institutions;
- (ii) Conduct evaluation meanwhile and also provide consultation to the same applicant;
- (iii) Do not avoid the possibility of interest of conflict, or jeopardy of the fair evaluation;
- (iv) Release secrecy of country, business and technology that is acquired at work;
- (v) Accept bribes, marketable securities and other illegal benefits;
- (vi) Draw false or untrue conclusion;
- (vii) Other behaviors violating laws and regulations.

Chapter IV Supervision and Administration

Article 24 [Responsibility of Supervision and Administration]

AQSIQ integrally supervises and administers the inspection activities by food inspection institutions.

CNCA is responsible for periodically organizing relevant departments to supervise and administer the food inspection institutions that have been granted the qualification criteria; CNCA should investigate and punish misconducts and violations by food inspection institutions. Provincial quality supervision and administration departments should report their decisions on food inspection institutions' misconducts and violations to AQSIQ and CNCA.

Article 25 [Responsibility of Supervision and Administration]

CNCA should supervise provincial quality supervision departments on the execution of qualification criteria of food inspection institutions.

Provincial quality supervision departments should periodically organize municipal and county level quality supervision departments to conduct supervisory inspections on food inspection institutions within their juristic territories. Municipal and county level quality supervision departments should conduct routine inspections on food inspection institutions within their juristic territories, and timely investigate and punish violations. Provincial quality supervision departments should report the decisions on illegal violations occurred within the juristic territories to AQSIQ and CNCA. Exit and Entry Inspection and Quarantine Bureaus immediately reporting to AQSIQ should routinely supervise and administer the subordinating food inspection institutions, and timely correct any violations and misconducts.

Article 26 [Capacity Verification]

AQSIQ, CNCA and provincial quality supervision departments should organize capacity verifications and inter-laboratory comparisons for food inspection institutions, so as to ensure that food inspection institutions can sustainably meet the requirements of qualification criteria. AQSIQ, CNCA and provincial quality supervision departments should encourage food inspection institutions to participate in the capacity verifications and inter-laboratory comparisons organized by international organizations and qualification evaluation institutions, so as to continuously improve the inspection qualification and capacity.

Article 27 [Regulations of Impartiality]

Food inspection institutions should be independent from the stakeholders involving in food inspection activities, and be free from any influence that may interference the technical judgment, and ensure the inspection data and results are free from the influence from other organizations and individuals.

Food inspection institutes are not allowed to recommend food to consumers in advertisement or any other forms.

Article 28 [Rules on Inspectional Personnel]

Food inspection institutions should assign inspectors to independently conduct food inspection. Inspectors having interest of conflict with the inspected party should withdraw.

Food inspectors should have no relationship of interest with inspected parties involving in inspection activities. Food inspectors are not allowed to participate in any activities that may jeopardize the independency and impartiality of the judgment.

Food inspectors should possess appropriate inspectional capability and qualification, and meet the qualification requirements set by pursuant regulations.

Article 29 [Responsibility System for Inspection]

Responsibility system of food inspection institutions and inspectors is imposed. Food inspection reports should be stamped by the food inspection institution and signed or stamped by the inspector (or authorized signer). Food inspection institutions and the inspectors are responsible for the issued food inspection reports.

Article 30 [Rules on Cancellation]

In any of the below circumstances, qualification granting departments should proceed the cancellation of a food inspection institution's qualification criteria certificate:

- (i) The certificate of qualification criteria is expired with no renewal application;
- (ii) The certificate of qualification criteria is expired, and (the food inspection institution) does not meet the requirements of renewals after a review;

- (iii) Lawful closure of the food inspection institution;
- (iv) Other circumstances where the certificate should be withdrawn according to laws and regulations.

Article 31 [Disclosure]

Food inspection institutions should establish appealing and complaint system, and lawfully handle controversial on the inspection conclusion raised by food enterprises, organizations such as food industry associations or consumers.

Any institutions and individuals reserve the rights to disclose illegal conducts and violations that food inspection institutions made to the qualification granting departments. Qualification granting departments should investigate and handle the issue in a timely manner, and protect the discloser in secrecy.

Chapter V Penalties

Article 32 [Penalty on Concealment]

In a case where an applicant conceals information or provides fraud or falsified material in the application for qualification criteria of food inspection institutions or renewal application, qualification granting departments should not proceed nor approve the application, and should issue a warning against the applicant. The applicant is not allowed to reapply for qualification criteria of food inspection institution within one year.

Article 33 [Penalty on Approval Cheating]

In the event where an applicant obtains a certificate of the qualification criteria of food inspection institution in improper manners such as fraud or bribery etc, the qualification granting department should withdraw the certificate. The applicant is not allowed to apply for the certificate of qualification criteria within three years.

Article 34 [Penalty on Unapproved Qualification Criteria]

Food inspection institutions that do not hold lawfully approved qualification criteria and issue food inspection data and results which can serve as testimonials will be subject to a penalty fine of RMB 30,000 Yuan. Quality and technology supervision departments at or above the county level shall oblige the correction and publicize the case.

Article 35 [Penalty of Qualification Criteria Suspension]

In any of the below circumstances, quality and technology supervision departments at or above county level should oblige the correction and impose penalty fine of less than RMB 30, 000 Yuan on the subject food inspection institution; in serious cases, to oblige the correction within designated period, and suspend the certificate of qualification criteria for three to six months. The subject food inspection institution is not allowed to issue food inspection reports during the certificate suspension period:

- (i) A food inspection institution does not continuously meet the requirements for qualification criteria to continue the food inspection activities;
- (ii) Violates this set of measures, increasing unapproved inspection items and issuing external food inspection reports;
- (iii) Accepts subsidy or behave in a way which will jeopardize the impartiality of the inspection;
- (iv) Leads to advert results from inspections in incompliance with food safety standards and inspection norms;
- (v) Takes the advantage of conducting inspection duties designated by the administrative authorities for inappropriate charges unfair competition.

Article 36 [Withdrawal of Qualification Criteria]

In any of the below circumstances, qualification granting departments should withdraw the

qualification criteria certificate from the subject food inspection institution:

- (I) Issues false or severely untrue food inspection reports;
- (II) Engages in food inspection activities beyond the approved scope;
- (III) Employs inspection staff members who are forbidden by law or administrative regulations to engage in food inspection;
- (IV) Issues external food inspection reports during the suspension of qualification criteria certificate;
- (V) Does not complete the corrections within the designated period, or does not meet the requirements for qualification criteria after correction;
- (VI) Other circumstances where the qualification criteria should be lawfully withdrawn.

Article 37 [Penalty on Inspection Personnel]

Food inspection personnel who issue false inspection reports are subject to penalty of removal from the position or dismissal. Food inspection personnel under criminal or dismissal penalty are not allowed to engage in food inspection duties in ten year after the criminal penalty completed or the date of the penalty decision being made.

Article 38 [Penalty Rules]

Food inspection institutions who recommend food to consumers in a manner of advertisement or other manners will be penalized in accordance with the second item of article 94 of the Food Safety Law of the People's Republic of China.

Article 39 [Supervision and Administration of Qualification Criteria Personnel]

Personnel with duties on qualification criteria and administration of food inspection institutions will be subject to administrative penalties in accordance to law for abuse of authority, dereliction of duty or irregularity for favoritism. Those who commit crimes will be subject to criminal penalty according to law.

Article 40 [Other Penalties]

Food inspection institutions are subject to penalties according to law for other illegal activities.

Chapter VI Supplementary Provisions

Article 41 [Applicable Regulations]

The qualification administration of institutions for agricultural product quality and safety inspection should be executed in accordance with the Agricultural Product Quality and Safety Law of the People's Republic of China.

Article 42 [Authority for Interpretation]

AQSIQ possesses the authority for interpreting this set of measures.

Article 43 [Effective Date]

This set of measures is to be effective October 1, 2010. Since the effective date, the Administration Measures for Qualification Criteria of Laboratories and Inspection Institutions (AQSIQ Order No. 86) will not be applicable to the qualification criteria of food inspection institutions.

END TRANSLATION

